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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,939	03/31/2004	Jimo Borjigin	056100-5035-US	4917
9629 7590 10/04/2007 MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004			EXAMINER EBRAHIM, NABILA G	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 10/04/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/812,939

Applicant(s)

BORJIGIN, JIMO

Examiner

Nabila G. Ebrahim

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 12-14 and 20-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 15-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 09/14/2006 and 10/13/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Receipt of Information Disclosure Statements dated 09/14/2006 and 10/13/2004.

Election/Restrictions

1. Applicant's election with traverse of Group Including claims 1-11 and 15-19 in the reply filed on 7/20/07 is acknowledged. The traversal is on the ground(s) that all three inventions involve a preselected biological condition controlled by a circadian clock. Accordingly, the search for one invention would overlap with the search for the other inventions. Therefore, it would not require undue burden for the Patent Office to search and examine all the claims in this application. This is not found persuasive because. This is not found persuasive because the examiner established serious burden by showing the different classification of the groups.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant while recites an agent that modulates a preselected biological condition

Art Unit: 1618

controlled by the circadian clock. The specification defines the agent as follows:

"the term agent refers to any compound which is pharmacologically active and/or modulates a biological condition in a subject". The specification does not describe the "agent" sufficiently, there are no examples of this "agent", no structure, and no mode of action that conveys a sense that Applicant had possession of the claimed invention.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites, "the preselected biological condition is tissue physiology", it is not clear how "physiology" which is the study of the functioning of living organisms can be a condition. The claim is vague.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1618

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1-11, and 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over **W. J. Drijfhout et al.** Exogenous melatonin entrains rhythm and reduces amplitude of endogenous melatonin: An in vivo microdialysis study, *Journal of Pineal Research* Volume 20 Issue 1 Page 24-32, January 1996 (Drijfhout) in view of **Josephine Arendt**, Melatonin and the pineal gland: influence on mammalian seasonal and circadian physiology, *Reviews of Reproduction* (1998) 3, 13-22 (Josephine) and further in view of **Xing SUN et al.** Circadian 5-HT production regulated by adrenergic signaling. *PNAS*. 2 April 2002, Vol. 99, No. 7, pages 4689-4691, see pages 1-15 (Sun).

Krijfhout teaches that the circadian rhythm of melatonin production was studied using on-line, in vivo microdialysis in the rat pineal gland. With this technique it was possible to record a pronounced melatonin rhythm with very high time resolution. Three phase-markers of the rhythm were calculated from the data, indicating increase (IT₅₀), decrease (DT₅₀) and amplitude of the rhythm. Comparing these phase markers led to several conclusions. The data presented provide us with new information about the nature of entrainment by melatonin.

Art Unit: 1618

Since the present development of melatonergic agents for clinical use focuses on the entrainment capacity, effects of these compounds on amplitude of circadian rhythms needs to be addressed. In vivo microdialysis seems to be a good technique for that (abstract). The study also discloses that the agents such as melatonin have an effect of sleep disorders (page 24). Regarding the surgery steps recited in claims 15-19, the reference teaches using a drill

One hole was drilled on each side of the temporal bone, inserting the probe of the monitoring device.

The reference briefly teaches that the circadian rhythm (clock) that produces melatonin was known and that the rhythm could be modulated by contacting the pineal by agents such as melatonin itself . The rhythm could be monitored by microdialysis as a good technique for the monitoring.

The study does not disclose the treatment of condition or disorders other than sleep disorders.

Josephine teaches that exogenous melatonin can entrain, circadian rhythms in rodents and humans. It can lower body temperature and induce transient sleepiness. These properties indicate that melatonin can be used therapeutically in circadian rhythm disorder. The reference also teaches that Successful outcomes have been reported, for example in jet lag and shift work, and with cyclic sleep disorder (abstract), insomnia, some problems of old age, and some psychiatric disorders (page 20).

The reference teaches the melatonin can be used as therapeutic agent for some conditions such as psychiatric problems and sleeping disorders.

Art Unit: 1618

Note that the steps recited in instant claim 1 which are: 1) monitoring an organ, 2) contacting the organ with an agent and 3) monitoring again to find out the effect are previously known in the art for detecting the effect of a drug and/or diagnosis of diseases such as the chemical stress test done for diagnosis of cardiovascular conditions.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use melatonin and/or its agonists to treat conditions such as sleeping disorders, behavioral problems and monitor its effect according to the method disclosed by Drijfhout.

Though the step of lifting the tissue over the pineal tissues is an expected step, it is noted that Drijfhout did not literally disclose this step.

Sun teaches Using on-line microdialysis, to monitor *in vivo* dynamics of pineal 5-hydroxytryptamine (5-HT; serotonin) release. Daily pineal 5-HT output is triphasic: (i) 5-HT levels are constant and high during the day; (ii) early in the night, there is a novel sharp rise in 5-HT synthesis and release, which precedes the nocturnal rise in melatonin synthesis; and (iii) late in the night, levels are low. To operate surgically on the subjects and use microdialysis, a circular opening was created in the skull by using a dental burr drill equipped with a shank diamond wheel point. The pia matter that covers the surface of the pineal was carefully removed to expose the pineal then the probe is inserted.

Applicant claims an improved surgical method, however, the claims does not reflect this improvement since Sun and Drijfhout recited the same steps.

Art Unit: 1618

The reference discloses the surgical steps for inserting monitoring probe of microdialysis in the pineal tissue.

Regarding claim 19, the different time periods recited would not limit the claims since it includes long term, short term, continuous or periodic. accordingly, any time terms disclosed in the references would read on the instant claim.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the surgical steps disclosed by Sun to insert the probe into the subject skill to monitor the output of the chemicals secreted by the pineal and the to monitor different biological conditions controlled by the circadian clock: The skilled artisan would expect favorable results in combining the surgical steps to the monitoring method to improve disorders controlled by the circadian rhythm.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1618

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nabila Ebrahim
9/27/07



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER